

K992623

NOV - 2 1999

## 510(k) Summary

**Trade Name:** Mitek Mini Anchor

**Sponsor:** Mitek Products  
60 Glacier Drive  
Westwood, MA 02090  
Registration #1221934

**Contact:** Paula E. Bulger  
Manager, Regulatory Affairs  
Mitek Products  
60 Glacier Drive  
Westwood, MA 02090  
Phone: (781) 251-2700  
Fax: (781) 461-9166

**Device Generic Name:** Staple, Fixation, Bone

**Classification:** According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

**Product Code:** JDR (21 CFR 888.3030)

**Predicate Devices:** K921873 - Mitek Mini Anchor  
K930892 - Mitek Mini Anchor  
K936311 - Mitek Mini Anchor

**Product Description:** The device described in this 510(k) is a sterile, disposable bone anchor consisting of a titanium alloy shaft with nickel-titanium shape-memory alloy arcs. The anchor is supplied pre-loaded with a polyester suture.

### Indications for Use:

Mitek Mini Anchors have been found substantially equivalent in previous Premarket Notifications for the following indications:

Shoulder: Bankart Repair  
Ankle: Midfoot Reconstructions  
Foot: Hallux Valgus Reconstruction  
Wrist: Scapholunate Ligament Reconstruction  
Hand: Ulnar or Lateral Collateral Ligament Reconstruction  
Pubis: Fixation in the pubis for bladder neck suspension to resolve stress urinary incontinence

This current 510(k) allows modification of the Mini Anchor labeling in order to add the following indication:

For the repair, repositioning or reattachment of soft tissues, ligament and tendons to the mandible for surgical stabilization of the TMJ articular disc.

### Safety and Performance:

The following safety and performance data has been provided to support substantial equivalence of the Mini Anchor for the expanded indication:

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Performance testing: Pull-out force (preserved human cadaver mandibular condyle)  
Strength comparison (Mini Anchor vs. bone tunnels in fresh frozen human mandible)

Long-term stability: Evaluation of osteointegration and positional stability in Mini Anchors used for new indication

Clinical data: Long-term patient follow-up evaluation of Mini Anchors used for new indication

**Conclusion:**

Based on safety and performance data, similarities in design, operating principle, materials, biocompatibility and sterilization method, the Mitek Mini Anchor with expanded indication has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Paula E. Bulger  
Regulatory Affairs Manager  
Mitek Products  
Ethicon, Inc.  
60 Glacier Drive  
Westwood, MA 02090

Re: K992623

Trade Name: Mitek Mini Anchor  
Regulatory Class: II  
Product Code: DZL  
Dated: August 4, 1999  
Received: August 5, 1999

Dear Ms. Bulger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

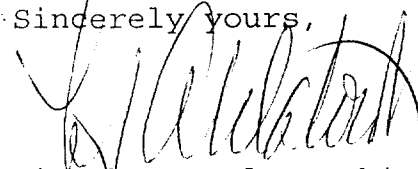
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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510(k) Number (if known): K992623

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The Mitek Mini Anchor is also indicated for the repair, repositioning or reattachment of soft tissues, ligaments and tendons to the mandible for surgical stabilization of the TMJ articular disc.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒   
(Per 21 CFR 801.109)

OR

Over-the -Counter Use ☐

Susan Runny

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number

K992623

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